

### **REMARKS**

Claims 1-10 are the pending claims in the present application. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Claims 1-10 are pending in the instant application.
2. Applicants confirm the provisional election with traverse made by David Halstead on June 20, 2003. Applicants elect with traverse the invention of Group I. The restriction requirement further contained a requirement to elect a species, and Applicants hereby confirm the election of hyaluronic acid with traverse and for search purposes only. In light of Applicants' election of the invention of Group I and the species of hyaluronic acid, claims 1-8 and 10 are currently under consideration.
3. Applicants' amendment to the specification is believed to obviate the objection to the specification.
4. Claims 4-7 are objected to under 37 CFR 1.75(c) and claims 5-7 are objected to under 37 CFR 1.75(c). Applicants' amendments to the claims are believed to obviate the objection.
5. Claims 1-8 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-19 of US Patent No. 6,207,718. Furthermore, claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over US Patent No. 6,207,718. Applicants traverse this rejection.

Applicants contend that the present application and the cited patent are currently owned by the same party. Accordingly, Applicants submission of a terminal disclaimer and a declaration under 37 CFR 1.130 will obviate these rejections. Given that the necessity for a terminal disclaimer is based on a comparison between the claims that will issue in this application and the previously issued claims, Applicants respectfully request that these grounds of rejection be held in abeyance until the indication of otherwise allowable subject matter. Following indication of otherwise allowable subject matter, Applicants will submit, if necessary, a terminal disclaimer and a declaration under 37 CFR 1.130.

6. Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

Applicants contend that claims 4-7 satisfy all of the requirements under 35 U.S.C. 112, second paragraph, and that one of skill in the art can readily appreciate the metes and bounds of the claimed subject matter. Nevertheless, to expedite prosecution, Applicants have amended claim 4. Applicant's amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

7. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Pepinsky et al. in view of Easton et al., and further in view of Usala et al. Applicants traverse this rejection, and furthermore Applicants contend that the rejection is moot in light of the amended claims.

Applicants maintain that the combination of references cited by the Examiner fail to render the claimed invention obvious. Although broadly enabling, the teachings of Pepinsky et al. fail to disclose the particular combinations of elements that characterize the claimed invention. These deficiencies are not overcome by Easton or Usala which provide nothing more than an invitation to one of skill in the art to attempt to arrive at Applicants' invention. Accordingly, these combinations of references are insufficient to undermine the patentability of Applicants' invention.

Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out certain embodiments of the invention. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. The amended claims are directed to a delayed release composition. Delayed release of hedgehog protein from various carriers allows numerous advantages for both in vitro and in vivo applications, and such advantages of a delayed release formulation are not contemplated by the prior art. Reconsideration and withdrawal are respectfully requested.

8. Applicants note that the references cited in this office action were previously supplied.
9. Applicants note that the references cited in the EPO Search Report had been previously cited by Applicants in an IDS filed June 30, 2002. Applicants note with appreciation that these references have been considered by the Examiner.

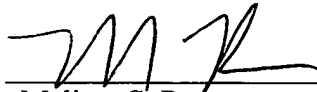
### CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: October 28, 2003

**Customer No: 28120**  
Docketing Specialist  
Ropes & Gray LLP  
One International Place  
Boston, MA 02110  
Phone: 617-951-7000  
Fax: 617-951-7050

Respectfully Submitted,



---

Melissa S. Rones  
Reg. No. 54,408